US008771276B2

(12) **United States Patent**
Linderman

(10) **Patent No.: US 8,771,276 B2**
(45) **Date of Patent: Jul. 8, 2014**

(54) **SYSTEMS AND METHODS FOR FORMING A CAVITY IN, AND DELIVERING CURABLE MATERIAL INTO, BONE**

(75) Inventor: **Evan D. Linderman**, Northbrook, IL (US)

(73) Assignee: **CareFusion 2200, Inc.**, San Diego, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 798 days.

(21) Appl. No.: **12/957,793**

(22) Filed: **Dec. 1, 2010**

(65) **Prior Publication Data**

US 2012/0143202 A1 Jun. 7, 2012

(51) **Int. Cl.**
A61B 17/88 (2006.01)
A61F 2/46 (2006.01)

(52) **U.S. Cl.**
USPC ..... **606/86 R**; 606/279

(58) **Field of Classification Search**
USPC ..... 606/86 R, 279, 92–94
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,969,888	A	11/1990	Scholten et al.	
5,108,404	A	4/1992	Scholten et al.	
5,827,289	A	10/1998	Reiley et al.	
5,972,015	A	10/1999	Scribner et al.	
6,048,346	A	4/2000	Reiley et al.	
6,066,154	A	5/2000	Reiley et al.	
6,235,043	B1	5/2001	Reiley et al.	
6,241,734	B1	6/2001	Scribner et al.	
6,248,110	B1	6/2001	Reiley et al.	
6,423,083	B2	7/2002	Reiley et al.	
6,558,390	B2 *	5/2003	Cragg	606/80
6,607,544	B1	8/2003	Boucher et al.	
6,623,505	B2	9/2003	Scribner et al.	
6,641,587	B2	11/2003	Scribner et al.	
6,663,647	B2	12/2003	Reiley et al.	
6,719,761	B1	4/2004	Reiley et al.	
6,726,691	B2	4/2004	Osorio et al.	
6,899,719	B2	5/2005	Reiley et al.	
6,923,813	B2	8/2005	Phillips et al.	
6,981,981	B2	1/2006	Reiley et al.	
7,044,954	B2	5/2006	Reiley et al.	
7,153,306	B2	12/2006	Ralph et al.	
7,156,861	B2	1/2007	Scribner et al.	
7,963,967	B1 *	6/2011	Woods	606/79
2006/0276819	A1	12/2006	Osorio et al.	
2007/0118142	A1	5/2007	Krueger et al.	
2007/0197971	A1	8/2007	Krueger et al.	
2007/0198024	A1	8/2007	Plishka et al.	
2008/0116224	A1	5/2008	Krueger et al.	
2008/0312637	A1	12/2008	Miller et al.	
2008/0319444	A9	12/2008	Osorio et al.	
2009/0043345	A1	2/2009	Mathews	

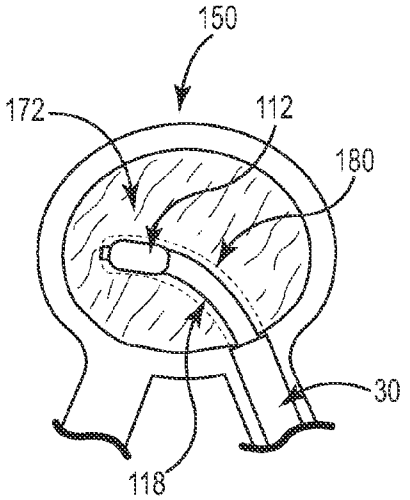
(Continued)

Primary Examiner — Anu Ramana
(74) *Attorney, Agent, or Firm* — Brinks Gilson & Lione

(57) **ABSTRACT**

Methods of injecting curable material within a bone structure, such as vertebroplasty, include locating a distal end of an access cannula within the bone structure. A channel creating device is inserted into a cannula lumen. A distal segment of the channel creating device is distally advanced from cannula distal end and into the bone structure. A curved channel is created in the bone structure with the distally advancing distal segment. A distal portion of a cavity creating device is then inserted into the cannula lumen, with the distal portion including an expandable body carried by an elongated body. The distal portion is distally advanced, following a path of the curved channel. The expandable body is transitioned to the expanded state to form a cavity in the bone structure. Finally, curable material is delivered to the cavity.

16 Claims, 12 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

2010/0087828 A1 4/2010 Krueger et al.
2010/0100099 A1 4/2010 Reilly et al.
2010/0100184 A1 4/2010 Krueger et al.
2010/0121336 A1 5/2010 Linderman et al.

* cited by examiner

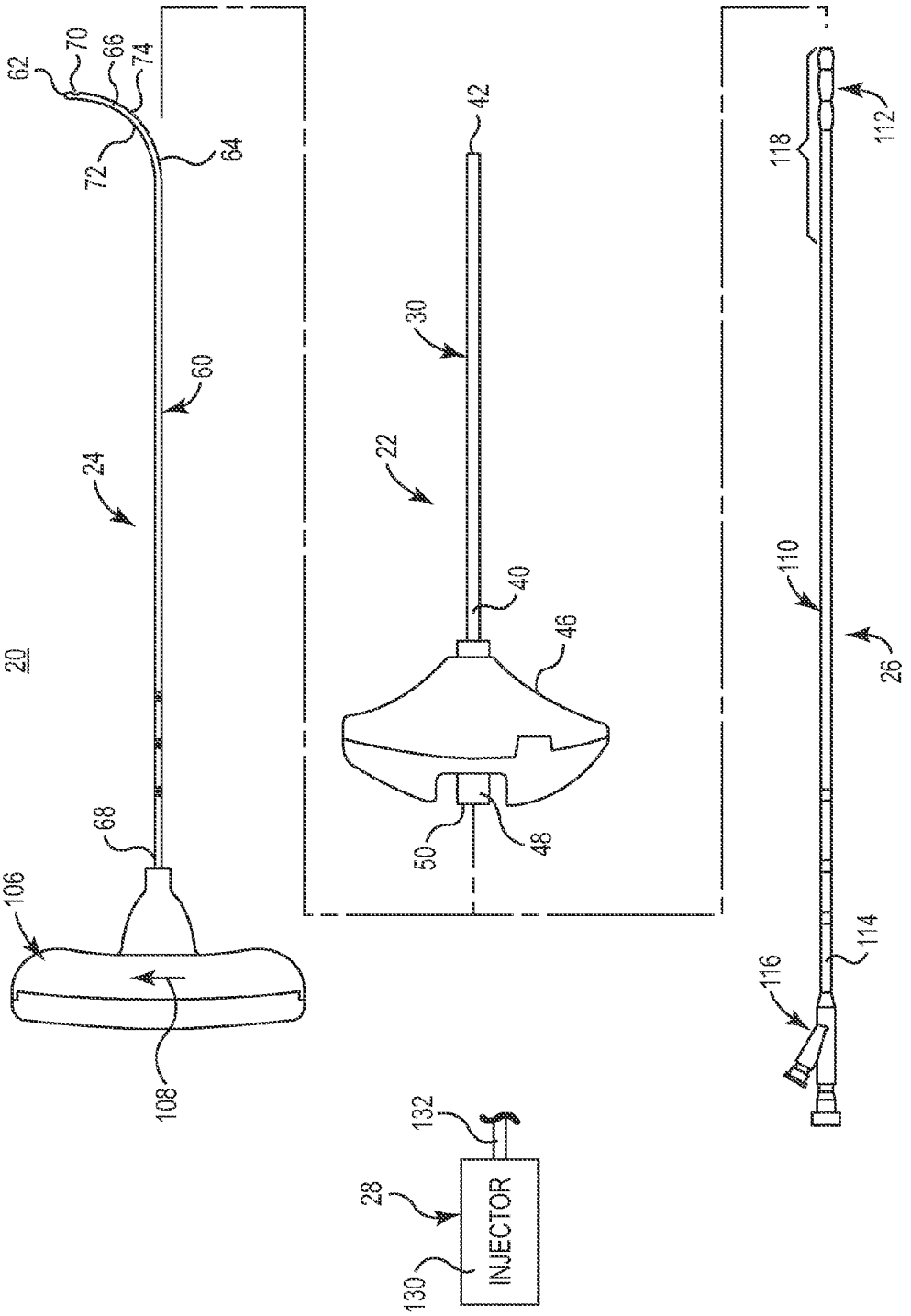

62
70
66
74
72
64
60
24
20
68
106
108
42
30
22
40
46
50
48
132
28
INJECTOR
130
118
112
110
26
114
116

Fig. 1

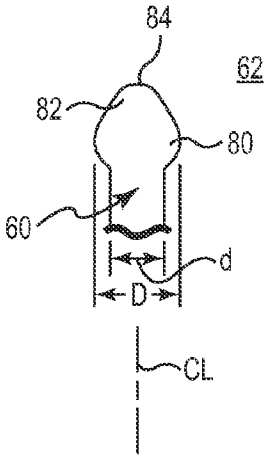


Fig. 2A

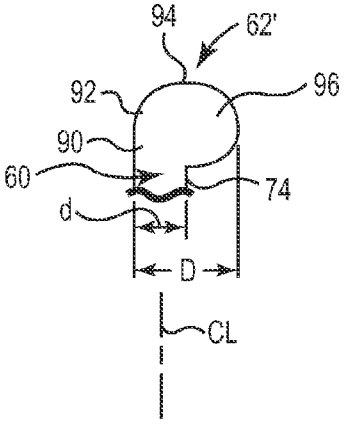


Fig. 2B

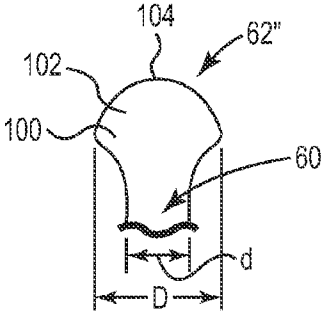


Fig. 2C

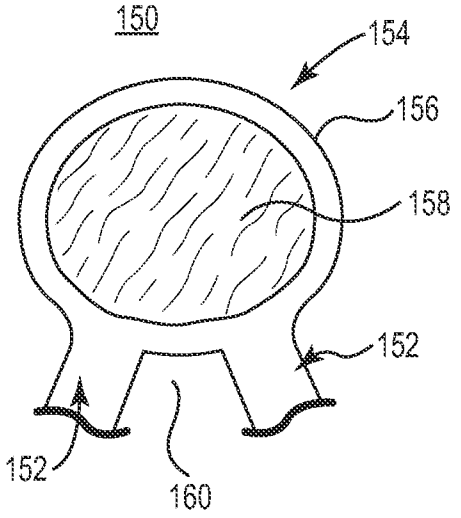


Fig. 3A

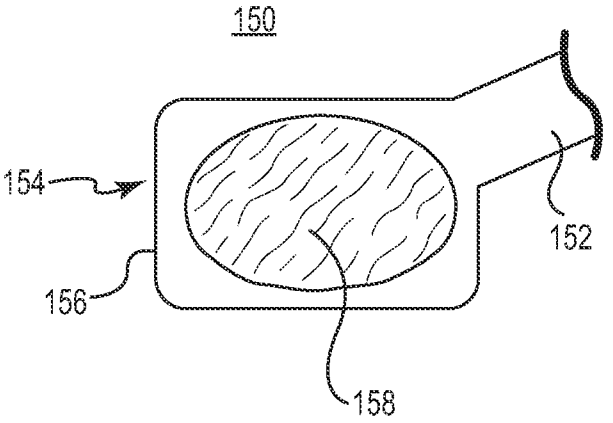


Fig. 3B

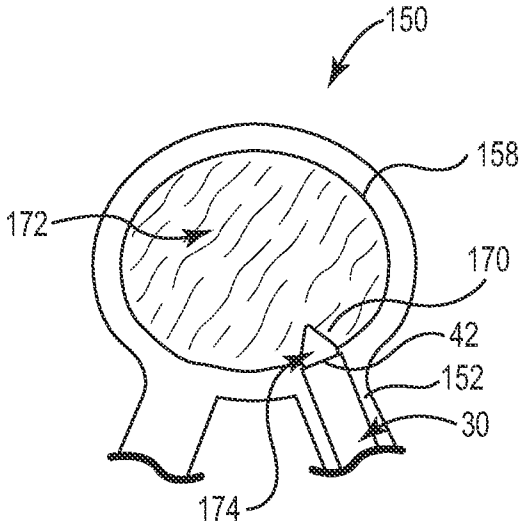


Fig. 4A

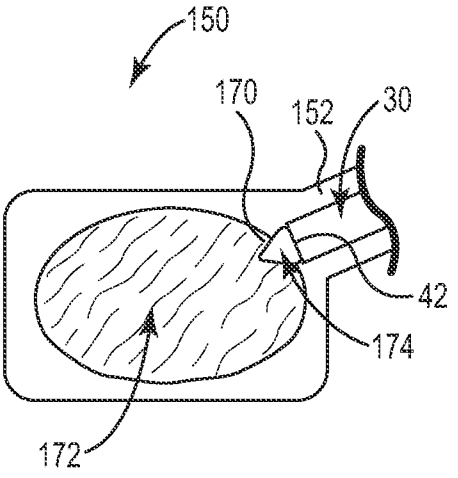


Fig. 4B

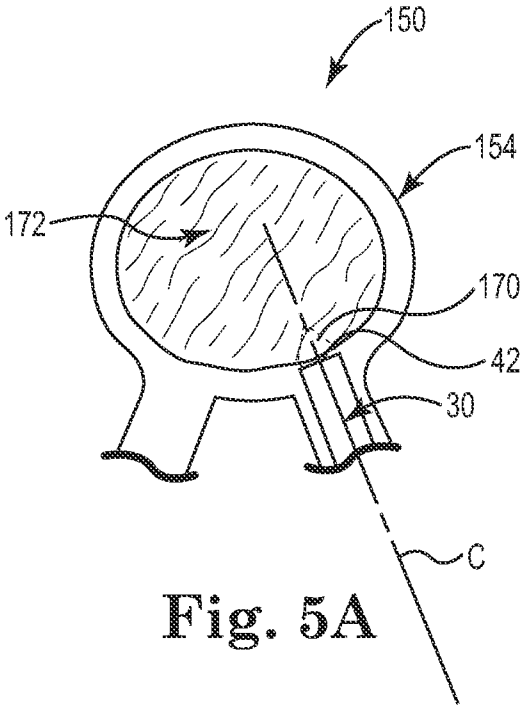


Fig. 5A

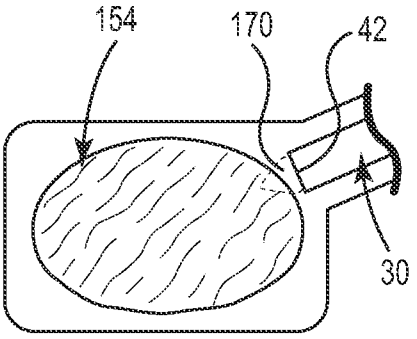


Fig. 5B

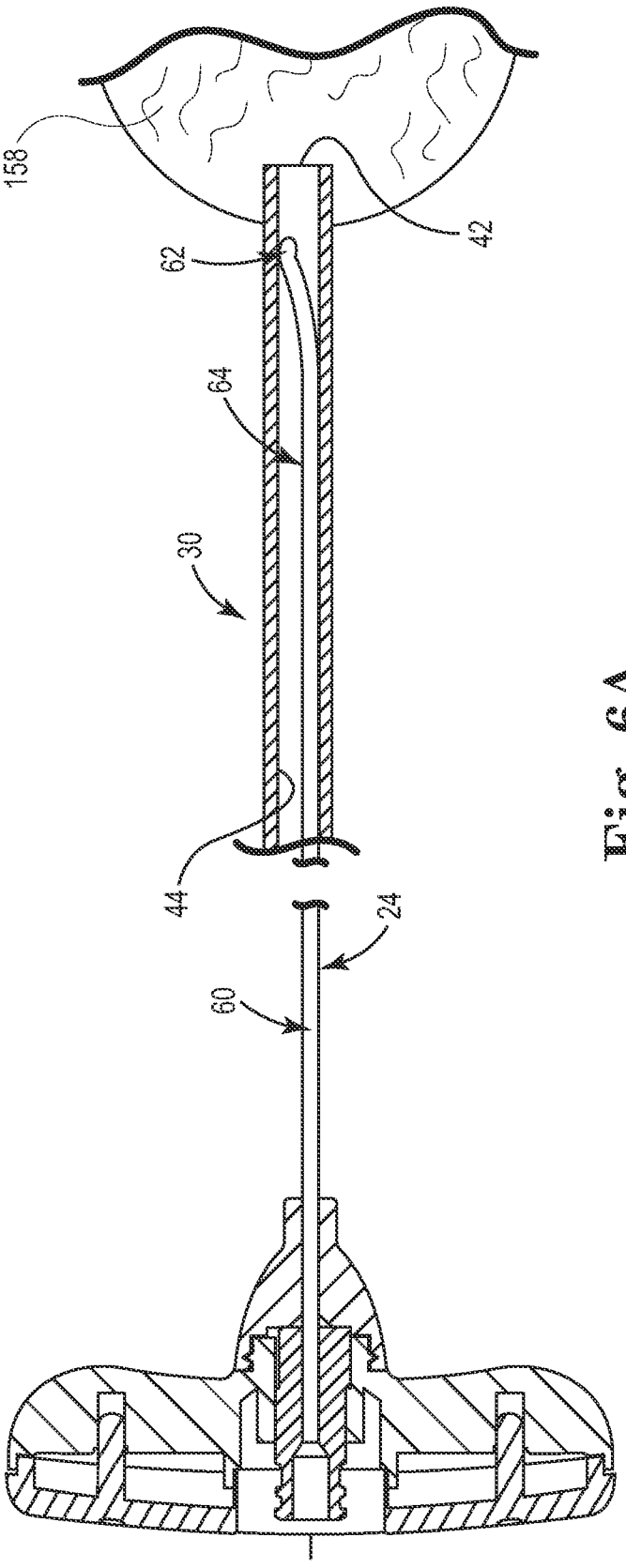


Fig. 6A

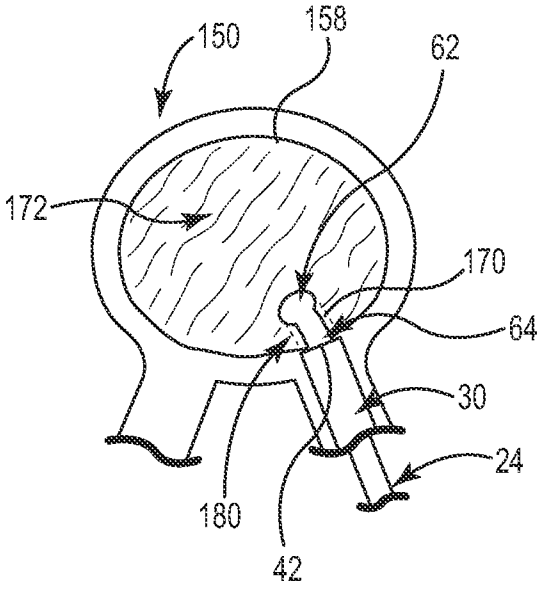


Fig. 6B

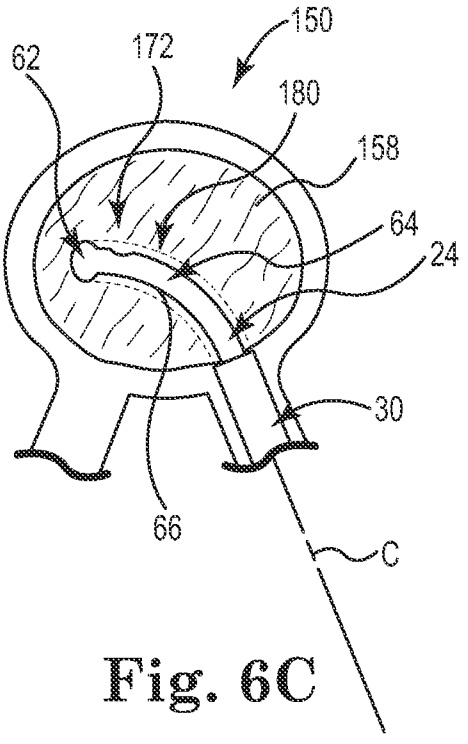


Fig. 6C

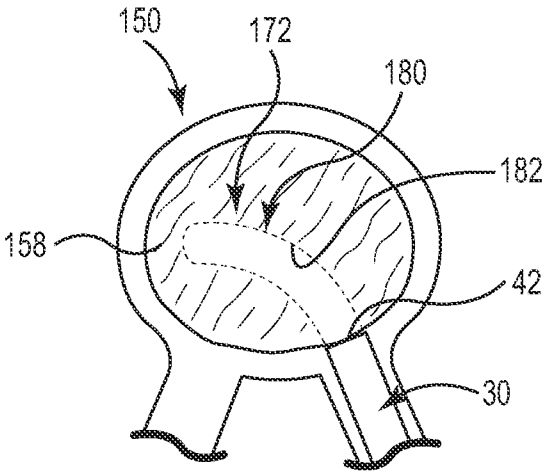


Fig. 7

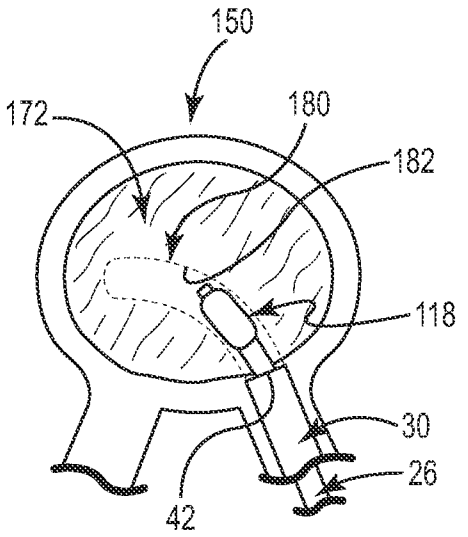


Fig. 8A

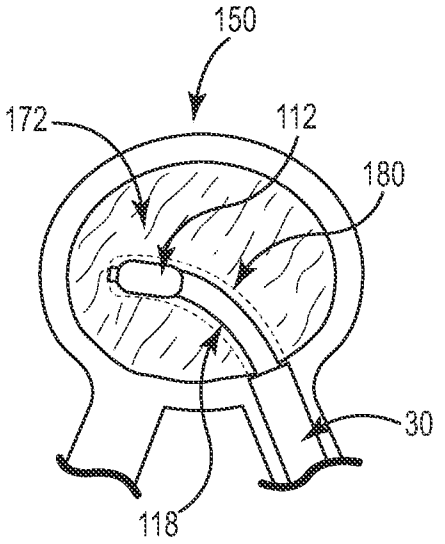


Fig. 8B

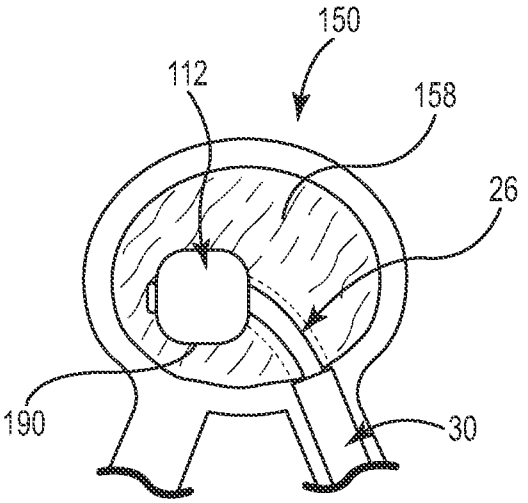


Fig. 9A

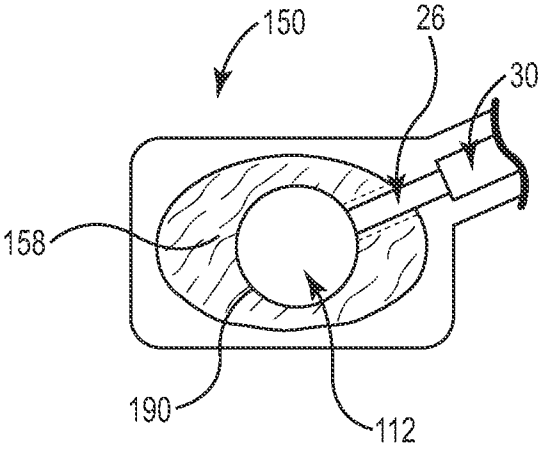


Fig. 9B

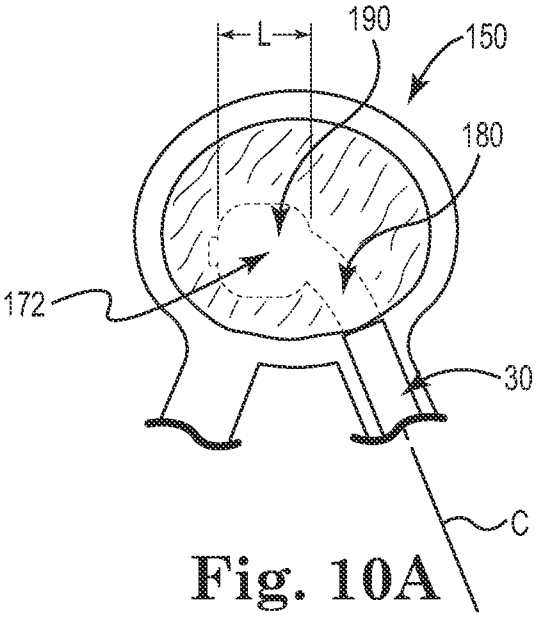


Fig. 10A

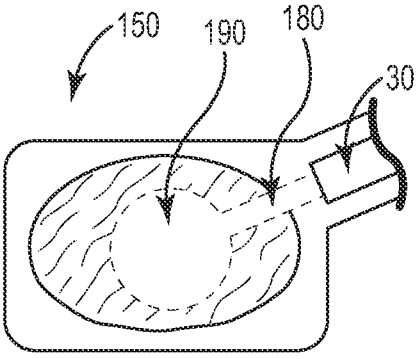


Fig. 10B

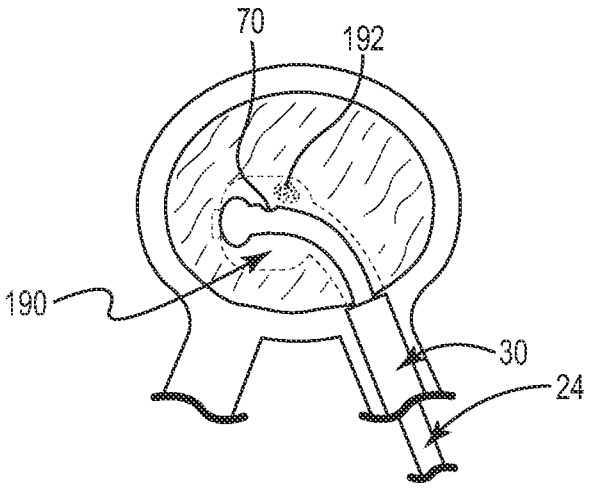


Fig. 11

SYSTEMS AND METHODS FOR FORMING A CAVITY IN, AND DELIVERING CURABLE MATERIAL INTO, BONE

BACKGROUND

The present disclosure relates to systems and methods for stabilizing bone structures. More particularly, it relates to systems and methods for forming a cavity inside a bone structure, such as a vertebral body, and delivering a stabilizing material into the cavity.

Surgical intervention at damaged or compromised bone sites has proven highly beneficial for patients, for example patients with back pain associated with vertebral damage.

Bones of the human skeletal system include mineralized tissue that can be generally categorized into two morphological groups: "cortical" bone and "cancellous" bone. Outer walls of all bones are composed of cortical bone, which has a dense, compact bone structure characterized by a microscopic porosity. Cancellous or "trabecular" bone forms the interior structure of bones. Cancellous bone is composed of a lattice of interconnected slender rods and plates known by the term "trabeculae".

During certain bone-related procedures, cancellous bone is supplemented by an injection of a palliative (or curative) material employed to stabilize the trabeculae. For example, superior and inferior vertebrae in the spine can be beneficially stabilized by the injection of an appropriate, curable material (e.g., PMMA or other bone cement or curable material). In other procedures, percutaneous injection of stabilization material into vertebral compression fractures, by, for example, transpedicular or parapedicular approaches, has proven beneficial in relieving pain and stabilizing damaged bone sites. Such techniques are commonly referred to as vertebroplasty. Other skeletal bones (e.g., the femur) can be treated in a similar fashion. Regardless, bone in general, and cancellous bone in particular, can be strengthened and stabilized by palliative insertion or injection of bone-compatible material.

Using vertebroplasty as a non-limiting example, a conventional technique for delivering the bone stabilizing material entails placing an access cannula with an internal stylet into the targeted delivery site (i.e., the vertebral body). The access cannula and stylet are used in conjunction to pierce the cutaneous layers above the hard tissue to be supplemented, then to penetrate the hard cortical bone of the vertebra, and finally to traverse into the softer cancellous bone underlying the cortical bone. Once positioned in the cancellous bone, the stylet is removed, leaving the access cannula in an appropriate, lodged position for delivery of curable material (e.g., via a needle or tube inserted through the access cannula) to the trabecular space of the vertebral body that in turn reinforces and solidifies the target site.

In some instances, an effectiveness of the procedure can be enhanced by forming a cavity or void within the cancellous bone, and then depositing the curable material in the cavity. For example, a balloon or other expandable device can be initially deployed and then expanded. This action, in turn, compresses cancellous bone to form a cavity. To minimize the duration of the procedure and number of tools required, it is desirable to use the same access cannula to first guide delivery of the cavity forming device, and subsequently to guide delivery of the curable material. Stated otherwise, one desirable procedure entails initially locating and lodging a distal end of the access cannula within the bone, immediately adjacent the target site. The cavity forming device is then delivered through the access cannula to the target site and then operated to form the cavity. In this regard, the access cannula is normally a metal tube rigidly defining a central axis. Conventional cavity forming devices typically include a longitudinally linear shaft carrying the expandable body. With this linear configuration, the shaft/expandable body progress from the access cannula into the bone structure along a relatively straight or linear path that is coaxial with the access cannula's central axis. While viable, this linear approach may inhibit the surgeon's ability to form the cavity at a desired location. For example, with vertebroplasty, the confined nature of the inner vertebral body and surrounding anatomy oftentimes necessitates insertion of the access cannula immediately adjacent one of the vertebra's pedicles. This access site, in combination with the linear configuration of the access cannula and expandable body-carrying shaft, dictates that the expandable body can only be located in a relatively limited area in line with the access cannula's central axis. In some instances, this restricted spatial location of the expandable body relative to the desired target site may not be optimal.

In light of the above, a need exists for improved systems and methods for forming a cavity in a compromised bone site, such as a vertebral body, and for delivering stabilizing material to the so-formed cavity.

SUMMARY

Some aspects in accordance with principles of the present disclosure relate to injecting curable material to a delivery site within a bone structure. The method includes locating a distal end of an access cannula within the bone structure. The access cannula forms a lumen and defines a central axis. A channel creating device is inserted into the lumen. A distal segment of the channel creating device is distally advanced from the distal end of the access cannula and into the bone structure. A curved channel is created in the bone structure with the distally advancing distal segment. In this regard, the curved channel defines a curve relative to the central axis. The channel creating device is removed. A distal portion of a cavity creating device is inserted into the access cannula lumen, with the distal portion including an expandable body carried by an elongated body. The expandable body is operable between a contracted state and an expanded state. During insertion into the access cannula, the expandable body is in the contracted state. The distal portion is then distally advanced from the distal end of the access cannula, with the distal portion of the cavity creating device following a path of the curved channel. The expandable body is transitioned to the expanded state to form a cavity in the bone structure. Finally, curable material is delivered to the cavity. In some embodiments, the expandable body is a balloon. In other embodiments, the distal segment of the channel creating device has a shape memory characteristic and naturally assumes a curved shape in longitudinal extension; in related embodiments, the distal segment deflects from the curved shape toward a more straightened shape when disposed within the access cannula, and naturally reverts toward the curved shape when distally extended from the access cannula. In yet other embodiments, the distal segment of the channel creating device includes a shaft terminating at a distal tip, with the distal tip configured to bore through bone structure with distal advancement from the access cannula.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a exploded side view of a system for forming a cavity in, and delivering curable material into, bone in accordance with principles of the present disclosure;

FIG. **2**A is an enlarged side view of a distal tip portion of a channel forming device component of the system of FIG. **1**;

FIG. **2**B is a simplified side view of another distal tip useful with the channel forming device of FIG. **1**;

FIG. **2**C is a simplified side view of another distal tip useful with the channel forming device of FIG. **1**;

FIG. **3**A is a simplified, transverse, sectional view of a vertebra upon which methods in accordance with principles of the present disclosure are useful;

FIG. **3**B is a simplified lateral sectional view of the vertebra of FIG. **3**A; and

FIGS. **4**A-**11** illustrate use of cavity formation and curable material delivery systems of the present disclosure in performing a bone stabilization procedure in accordance with principles of the present disclosure.

DETAILED DESCRIPTION

One embodiment of a curable material delivery system **20** in accordance with principles of the present disclosure is shown in FIG. **1**. The system **20** includes an access cannula assembly **22**, a channel forming device **24**, a cavity forming device **26**, and a material delivery device **28**. Details on the various components are provided below. In general terms, however, the access cannula assembly **22** includes an access cannula **30** for insertion into a bone site of interest in a patient (e.g., a vertebra). Once the access cannula **30** is desirably located relative to the bone site, a portion of the channel forming device **24** is delivered to the bone site via the access cannula **30**, and operated to form a curved channel. The channel forming device **24** is then replaced with the cavity forming device **26**, and operated to form a cavity along the curved channel. The material delivery device **28** is then operated to deliver curable material to the cavity via the channel forming device **24**, the access cannula **30** and/or an additional delivery tube. The system **20** and related methods of use facilitate formation of the material-receiving cavity (and thus injection of the curable material) at a location laterally displaced from a central axis of the access cannula **30**.

The system **20** can be used for a number of different procedures, including, for example, vertebroplasty and other bone augmentation procedures in which curable material is delivered to a site within bone, as well as possibly to remove or aspirate material from a site within bone. The system **20** is highly useful for delivering a curable material in the form of a bone curable material. The phrase "curable material" within the context of the substance that can be delivered by the system **20** of the present disclosure is intended to refer to materials (e.g., composites, polymers, and the like) that have a fluid or flowable state or phase and a hardened, solid or cured state or phase. Curable materials include, but are not limited to, injectable bone cements (such as polymethylmethacrylate (PMMA) bone curable material), which have a flowable state wherein they can be delivered (e.g., injected) by a cannula to a site and subsequently cure to hardened, cured material. Other materials such as calcium phosphates, bone in-growth materials, antibiotics, proteins, etc., can be used in place of, or to augment, bone cement (but do not affect an overriding characteristic of the resultant formulation having a flowable state and a hardened, solid, or cured state). This would allow the body to reabsorb the curable material and/or improve the clinical outcome based on the type of filler implant material.

As mentioned above, the access cannula assembly **22** includes the access cannula **30**. The access cannula **30** is provided to be positioned in (or immediately proximate), a target site for delivery of curable material therein. The access cannula **30** can be made of a surgical grade of stainless steel, but may be made of known equivalent materials that are both biocompatible and substantially non-compliant at expected operating pressures. The access cannula **30** defines a proximal portion **40**, a distal end **42**, and a lumen **44** (hidden in FIG. **1**, but shown in FIG. **6**A) to allow various equipment, such as the channel forming device **24**, the cavity forming device **26**, a stylet (not shown), etc., to pass therethrough. In some constructions, the distal end **42** is blunt, but can alternatively be beveled to ease the penetration of the access cannula **30** through the cutaneous and soft tissues, and especially through hard tissues.

Surrounding the proximal portion **40** of the access cannula **30** is an optional handle **46** for manipulating the access cannula **30** and connecting the access cannula **30** with one or more of the devices **24**-**28**. In some constructions, the access cannula assembly **22** further includes a handle connector **48**. The handle connector **48** is fluidly connected to the lumen **44**, and defines a proximal end **50** of the access cannula **30**. Alternatively, the handle connector **48** can incorporate features forming part of a locking mechanism component of the system **20**. For example, the handle connector **48** can optionally include a luer-lock type of connector, but other known connecting mechanisms may be successfully interchanged (e.g., a conventional threaded hole, a threaded locking nut arrangement, etc.). Features of the optional locking mechanism are described in U.S. Publication No. 2007/0198024 entitled "Curable Material Delivery Device" and the entire teachings of which are incorporated herein by reference. In other embodiments, the handle **46** and/or the handle connector **48** can be omitted.

The channel forming device **24** is configured to form a channel within bone, and generally includes an elongated shaft **60** distally connected to or forming a distal tip **62**. The elongated shaft **60** can be a solid body or a tube. Regardless, the elongated shaft **60** includes a distal segment **64** (referenced generally) defining a pre-set curve or bend **66**. As described below, the distal segment **64**, and in particular the bend **66**, is deflectable, and has a shape memory attribute whereby the distal segment **64** can be forced from the curved shape (shown in FIG. **1**) toward a more straightened shape, and will naturally revert back to or toward the curved shape upon removal of the force.

The elongated shaft **60** defines a continuous length between a proximal end **68** and the distal tip **62**, with the deflectable distal segment **64**, and in particular the bend **66**, extending along approximately 10%-50% of a length of the elongated shaft **60** as measured from the distal tip **62**. To facilitate formation of a curved channel within a confined bone site (such as with a vertebroplasty procedure), the deflectable distal segment **64** can be formed to define the bend **66** at a predetermined radius of curvature appropriate for the procedure in question. In one construction, the bend **66** is J-shaped (approximating at least a 60° bend). Alternatively, the bend angle can be greater or lesser depending upon the particular procedure for which the channel forming device **24** is to be employed.

To facilitate ready deflection of the deflectable distal segment **64** from the curved shape toward a more straightened state (such as when the elongated shaft **60** is inserted within the access cannula **30**) and self-reversion back to or toward the curved shape, the elongated shaft **60**, or at least the deflectable distal segment **64**, is formed of a shape memory material. In some constructions, the elongated shaft **60**, or at least the distal segment **64**, comprises Nitinol™, a known shape memory alloy of nickel and titanium. For example, the bend **66** can be formed in the distal segment **64** by deforming

a straight wire or tube under extreme heat for a prescribed period of time, which pre-sets a curved shape in the distal segment **64**. Alternatively, the pre-set curve or bend **66** can be formed in an initially straight wire or tube by cold working the straight shaft and applying a mechanical stress. Cold working permanently locks a crystalline structure (for example, a partial martensitic crystalline structure) in a portion (i.e., the deflectable distal segment **64**) of the shaft, while an unstressed portion remains in, for example, an austenitic structure.

In addition to Nitinol™, other materials exhibiting the above-described shape memory behavior can be employed, including super elastic or pseudoelastic copper alloys, such as alloys of copper, aluminum, and nickel, and alloys of copper, aluminum, and zinc, and alloys of copper and zinc. The deflectable distal segment **64** is formed to be resilient and to naturally assume the desired radius of curvature. In this manner, after the elongated shaft **60**, and in particular the deflectable distal segment **64**, is flexed or deflected to a substantially straightened shape (not shown), upon subsequent relaxation, the deflectable distal segment **64** "remembers" the pre-set curved shape and relaxes/returns to the bend **66** as described in greater detail below. In yet other embodiments, the curved shape of the distal segment **64** can be effectuated by one or more additional bodies or mechanisms, such as an internal pull wire. Regardless, the elongated shaft **60**, including the distal segment **64**, is longitudinally rigid such that a distal pushing force applied at or adjacent the proximal end **68** is transferred to the distal tip **62**. The longitudinal rigidity of the shaft **60** is such that when the distal tip **62** is in contact with cancellous bone and the pushing force is sufficient for the distal tip **62** to bore through cancellous bone, the shaft **60** will not longitudinally buckle or collapse.

With embodiments in which the elongated shaft **60** is a tube, one or more side orifices **70** can be provided adjacent the distal tip **62**, extending through a thickness of a side wall of the tubular elongated shaft **60**. In one construction, a single orifice **70** is provided, and is located "opposite" a direction of the bend **66**. In other words, relative to the longitudinal view of FIG. **1**, a direction of the bend **66** serves to form the elongated shaft **60** to define an interior bend side **72** and an exterior bend side **74**. With these designations in mind, the side orifice **70**, where provided, is optionally disposed along the exterior bend side **74**. Material (e.g., curable material) can be dispensed from the side orifice(s) **70**, and/or material (e.g., bone) can be aspirated into the side orifice(s) **70**. In other embodiments, the side orifice(s) **70** can be omitted. In yet other embodiments, the elongated shaft **60** is a solid body or wire.

The distal tip **62** can assume various forms configured to effectuate boring through bone (and in particular cancellous bone). More particularly, in some embodiments, the channel forming device **24** effectuates formation of a channel in cancellous bone by forcibly advancing the distal tip **62** through the bone material. With this technique, the elongated shaft **60** is not rotated or otherwise operated to mechanically cut the bone tissue; instead, the forced advancement of the distal tip **62** compacts and/or or crushes bone material in contact therewith to thereby create a space or channel.

With the above explanation in mind, one construction of the distal tip **62** in accordance with the present disclosure is shown in FIG. **2**A. The distal tip **62** has an obround shape, tapering in diameter from an intermediate portion **80** to a leading portion **82**. The leading portion **82** terminates at a leading end **84** that can be blunt or sharpened. Regardless, the intermediate portion **80** defines a maximum diameter D of the distal tip **62**, with this maximum diameter D being greater than a diameter d of the elongated shaft **60**, and in particular along the distal segment **64**. However, the maximum diameter D is at least slightly smaller than a diameter of the access cannula lumen **44** (FIG. **6**A), such that the channel forming device **44** (FIG. **1**), and in particular the distal segment **64** (FIG. **1**), can be slidably received through the access cannula **30** (FIG. **1**). With the construction of FIG. **2**A, a shape of the distal tip **62** is symmetrical relative to a centerline CL defined by the elongated shaft **60**.

Another embodiment distal tip **62'** in accordance with principles of the present disclosure is shown in FIG. **2**B. The distal tip **62'** includes an intermediate portion **90** and a leading portion **92** terminating at a leading end **94**. Once again, the leading end **94** can be blunt or sharpened. Further, the intermediate portion **90** defines a maximum diameter D of the distal tip **62'** that is greater than the diameter d of the elongated shaft **60**, but slightly less than a diameter of the access cannula lumen **44** (FIG. **6**A). With the configuration of FIG. **2**B, however, a shape of the distal tip **62'** is asymmetric relative to the centerline CL of the elongated shaft **60**. Effectively, then, the distal tip **62'** forms a protrusion or bulge **96** extending from one side of the elongated shaft **60**. In some embodiments, the protrusion **96** is defined along the exterior bend side **74** (referenced generally in FIG. **2**B and shown in greater detail in FIG. **1**). Alternatively, the protrusion **96** can project relative to a different side of the elongated shaft **60**.

Yet another embodiment distal tip **62"** in accordance with principles of the present disclosure is shown in FIG. **2**C. The distal tip **62"** includes an intermediate portion **100** and a leading portion **102** terminating at a leading end **104**. The distal tip **62"** is akin to the distal tip **62** (FIG. **2**A) described above, but presents a more distinct taper to the leading end **104**. Once again, the leading end **104** can be blunt or sharpened, and the intermediate portion **100** defines a maximum diameter D that is greater than the diameter d of the elongated shaft **60** yet slightly smaller than the diameter of the access cannula lumen **44** (FIG. **6**A).

The distal tips **62-62"** (FIGS. **2**A-**2**C) described above represent non-limiting examples in accordance with the present disclosure. In more general terms, the distal tip **62** can have any shape appropriate for boring through cancellous bone when forcibly advanced through the cancellous bone.

Returning to FIG. **1**, the channel forming device **24** can optionally include other components, such as a handle **106** attached to the proximal end **68** of the elongated shaft **60**. Where provided, the handle **106** facilitates application of a pushing force onto the shaft **60**. Further, the handle **106** can include indicia **108** that visually indicates a direction of the bend **66**, and the handle **106** can be adapted to interface with the handle connector **48** of the access cannula assembly **22**. In other embodiments, the handle **106** is omitted.

The cavity forming device **26** can assume various forms appropriate for forming a void or cavity within bone, and generally includes an elongated body **110** distally connected to or forming a working end **112**. The elongated body **110** is sized to be inserted within access cannula lumen **44** (FIG. **6**A), and can include one or more tubes, shafts, etc., necessary for operation of the working end **112**.

A proximal region **114** of the elongated body **110** is optionally connected to or forms a connector **116**. The connector **116** can assume various forms, such as the Y-type connector shown that provides ports fluidly open to various lumen(s) of the elongated body to facilitate operation of the working end **112**. Optionally, the connector **116** can include or form features conducive to selective, rigid attachment to the handle connector **48** as described above (e.g., the connector **116** and

the handle connector **48** collectively form a locking mechanism). In other embodiments, the connector **116** is omitted.

The working end **112** can include one or more components for forming a cavity or void within bone. For example, in some constructions, the working end **112** includes one or more expandable or inflatable members (e.g., a single balloon, multiple balloons, a single balloon with two or more discernable inflation zones, etc.), constructed to transition between a contracted (e.g., deflated) state in which the working end/balloon **112** can be passed through the access cannula lumen **44** (FIG. **6**A), and an expanded (e.g., inflated) state in which the working end/balloon **112** expands and compacts contacted cancellous bone. In this regard, a size and shape of the working end/balloon **112** can be predetermined and/or restrained with one or more additional components (not shown), such as internal and/or external restraints. Regardless, the working end/balloon **112** is structurally robust, able to withstand (e.g., not burst) expected inflation pressures when in contact with cancellous bone.

The cavity forming device **26** can include one or more additional components connected or operable through the proximal region **114** for actuating the working end **112**. By way of one non-limiting example, then, the cavity forming device **26** can include a source (not shown) of pressurized fluid (e.g., contrast medium) for inflating the balloon(s) carried or formed by the working end **112**. A hand-held syringe-type pump can be used as the pressurized source.

With constructions of the cavity forming device **26** incorporating a balloon(s) as the working end **112**, at least a distal region **118** (including the working end/balloon **112** and corresponding portion of the elongated body **110**) is relatively flexible, and readily conforms to different shapes (in longitudinal extension) in response to external forces. Thus, while FIG. **1** illustrates the distal region **118** as being relatively linear in longitudinal extension, the distal region **118** will conform to multiple other shapes, such as the shape of a curved channel formed in cancellous bone as described in greater detail below. For example, the elongated body **110** can be a catheter-type, flexible tube forming one (or more) ports that are fluidly open to an interior of the balloon **112**. With these embodiments, the catheter body **110** exhibits sufficient longitudinal rigidity to facilitate distal movement of the balloon **112** through a channel, with the distal region **118** following or conforming to a path of the channel.

The material delivery device **28** includes a source **130** of curable material that can assume various forms appropriate for delivering the desired curable material. Typically, the source **130** of curable material comprises a chamber filled with a volume of curable material and employing any suitable injection system or pumping mechanism to transmit curable material out of the chamber. For example, a hand injection system can be used where a user applies force by hand to an injector. The force is translated into pressure on the curable material, forcing the curable material to flow out of the chamber. A motorized system may also be used to apply force.

Tubing **132** is fluidly connected to, and extends from, the source **130** of curable material, and serves as a conduit through which the curable material is delivered. In some embodiments, the tubing **132** is configured for connection to the channel forming device **24**, with the channel forming device **24**, in turn, being employed to deliver the curable material to the delivery site. In other embodiments, the tubing **132** can be directed through the access cannula **30** to deliver the curable material directly to the delivery site. In yet other embodiments, a separate delivery tool (e.g., a delivery cannula) can be provided, having a deflectable, distal section forming a bend commensurate with the bend **66** of the channel forming device **24** as described above. With these optional embodiments, the delivery cannula is employed to deliver the curable material, via connection to the tubing **132**, to the delivery site.

Regardless of an exact configuration, systems **20** in accordance with principles of the present disclosure are useful in performing a wide variety of bone stabilizing procedures by injecting or delivering curable material into bone. For example, the systems **20** of the present disclosure can be employed with vertebra-related procedures (e.g., vertebroplasty). To this end, FIGS. **3**A and **3**B are simplified views of a vertebra **150**. As mentioned above, bone stabilization via delivery or injection of curable material has been found to be beneficial in the treatment of defects of the vertebra **150**. In general terms, the vertebra **150** includes pedicles **152** and a vertebral body **154** defining a vertebral wall **156** surrounding bodily material **158** (e.g., cancellous bone, blood, marrow, and soft tissue). The pedicles **152** extend from the vertebral body **154** and surround a vertebral foramen **160**. As a point of reference, systems and methods of the present disclosure are suitable for accessing a variety of bone sites. Thus, while the vertebra **150** target site is illustrated, it is to be understood that other bone sites can be accessed and treated by systems and methods of the present disclosure (i.e., femur, long bone, rib, sacrum, etc.).

With the anatomy of the vertebra **150** in mind, some methods in accordance with principles of the present disclosure entail the access cannula **30** being initially employed to form an insertion access path **170** generally directed toward to a target site **172** as shown in FIGS. **4**A and **4**B. In this regard, the insertion access path **170** can be formed through one of the pedicles **152** and into the bodily material **158** adjacent the target site **172**. Thus, as illustrated, the access cannula **30** has been driven through the pedicle **152** via a transpedicular approach. The transpedicular approach locates the access cannula **30** between the transverse process and mammillary process of the selected vertebra **150**. Alternatively, other approaches toward the target site **172** can be employed (e.g., an anterior approach). In any event, the access cannula **30** provides general access to the target site **172** at the open, distal end **42**. As shown, a stylet **174** can be employed to assist in forming the insertion access point or path **170** toward the target site **172**. Alternatively, or in addition, the access cannula **30** alone can be configured to sufficiently achieve the insertion access path **170**. In yet other embodiments, a separate, outer guide cannula (not shown) can initially be deployed to form the insertion access path **170**. Regardless, once positioned, the access cannula **30** can remain relatively stationary relative to the target site **172**. Where provided, the stylet **174** is removed from the access cannula **30** resulting in the arrangement of FIGS. **5**A and **5**B. As shown, the access cannula **30** is retained at the vertebral body **154**, with the distal end **42** generally facing the target site **172**. However, the intended or desired target site **172** is transversely offset from the access cannula **30**. More particularly, and as best reflected in FIG. **5**A, a central axis C of the access cannula **30** does not pass directly through the intended target site **172**.

With reference to FIGS. **6**A-**6**C, the channel forming device **24** is deployed through the access cannula **30** to create a curved channel **180** (referenced generally in FIG. **6**C) in the cancellous bone (or other bodily material) **158**. In particular, the distal segment **64** of the channel forming device **24** is slidably inserted/distally advanced within the access cannula **30**. As illustrated generally in FIG. **6**A, the distal tip **62** of the channel forming device **24** is poised at the distal end **42** of the access cannula **30**. Prior to further distal movement, the distal segment **64**, is entirely within the access cannula lumen **44**,

such that the distal segment **64** is constrained (e.g., deflected or flexed) to a more straightened shape that generally conforms to a shape of the access cannula **30**. The force is effectively imparted by the access cannula **30** onto the deflectable distal segment **64** due to the radius of curvature defined by the distal segment **64** in a "natural" state being larger than a diameter of the access cannula lumen **44**. This interaction essentially "removes" the pre-set curvature of the bend **66** (FIG. **1**), forcing or rendering the deflectable distal segment **64** to a more straightened state (it being understood that because an inner diameter of the access cannula **30** is greater than the diameter d (FIG. **2**A) of the elongated shaft **60** as well as slightly greater than the maximum diameter D (FIG. **2**A) of the distal tip **62**, the distal segment **64** may continue to have a slight curvature within the access cannula **30**). Thus, "substantially straightened" is in reference to the elongated shaft **60** being substantially, but not necessarily entirely, linear. Prior to interaction with the cancellous bone material **158**, then, the elongated shaft **60** is flexed toward a substantially or more straightened state within the access cannula **30**.

The channel forming device **24**, and in particular the distal segment **64** is then distally advanced within the access cannula **30**, such that at least a portion of the distal segment **64** extends beyond the open distal end **42** of the access cannula **30** and into the cancellous bone **158** immediately adjacent the insertion access path **170** as shown in FIG. **6**B. The now unrestrained portion of the distal segment **64** naturally deflects laterally (from the more straightened shape described above) upon exiting the access cannula distal end **42**, self-reverting to or toward the pre-set curvature of the bend **66** previously described due to, for example, the shape memory characteristic. In addition, with distal advancement of the distal segment **64**, the distal tip **62** intimately contacts and effectively compacts or crushes the cancellous bone **158**. Stated otherwise, the area of cancellous bone **158** directly contacted by the advancing distal tip **62** is permanently deformed or compacted, resulting in formation of the channel **180**. Taken in combination, then, the channel forming effects of the distal tip **62** and the pre-set curved shape of the distal segment **64** produce or generate the curved channel **180** in response to a distally-directed pushing force applied to the proximal end **68** (FIG. **1**) of the channel forming device **24** in a direction generally co-axial with the central axis C of the access cannula **30** as shown in FIG. **6**C. The pushing force is translated to the distal tip **62**, and is of sufficient magnitude to cause compaction or crushing of the contacted cancellous bone **158**. Further, the self-reverting curved shape of the distal segment **64** effectively "directs" the distal tip **62** through a curved or arcuate path while boring through the cancellous bone **158**. Advancement of the distal segment **64** continues until the distal tip **62** is located at, or approximately at, the target site **172**. Notably, the channel forming device **24** creates the curved channel **180** independent of any naturally occurring "paths" within the cancellous bone **158**. For example, the natural anatomy of the cancellous bone (and/or naturally-occurring debris within the vertebral body **154**) may tend to inherently direct an otherwise flexible tube (with no pre-set longitudinal curve) toward the target site **172** or away from the target site **172**, somewhat like a grown pattern in wood. Under either circumstance, the channel forming device **24** and corresponding methods of use of the present disclosure definitely achieve the curved channel **180** as a direct function of the present curve in the channel forming device **24**. Thus, the present disclosure is distinct from a non-linear channel formed by a flexible tube that simply happens to deflect when encountering the natural anatomy.

The channel forming device **24** is then removed from the access cannula **30**, resulting in the curved channel **180** as shown in FIG. **7**. The curved channel **180** is defined through or in the cancellous bone **158**, and is fluidly open to the access cannula distal end **42**. Due to the compaction caused by the distal tip **62** (FIG. **6**C), the cancellous bone **158** "surrounding" the curved channel **180** effectively serves as or provides a discernable perimeter or wall **182**.

The cavity forming device **26**, and in particular the distal region **118**, is then inserted through, and distally advanced from, the access cannula **30** as shown in FIG. **8**A. In this regard, as portions of the distal region **118** exit the access cannula distal end **42**, the distal region **118** follows a path of the curved channel **180**. More particularly, the distal region **118** is sufficiently flexible such that upon contacting the channel wall **182** and with further distal advancement, the distal region **118** readily deflects, thereby tracking or following the shape of the curved channel **180**. In other words, the distal region **118** follows the path of least resistance, and does not bore through the cancellous bone **158** surrounding the curved channel **180**. Distal advancement of the distal region **118** continues through the curved channel **180**, resulting in the arrangement of FIG. **8**B. In the final location, the working end **112** is at or immediately proximate the target site **172**.

With reference to FIGS. **9**A and **9**B, the cavity forming device **26** is operated to cause the working end/balloon **112** to form a cavity or void **190** (referenced generally) in the cancellous bone (or other bodily material) **158**. For example, the working end/balloon **112** can be expanded (e.g., inflated). The working end/balloon **112** is then transitioned to the contracted state (e.g., deflated), and removed from the access cannula **30**. FIGS. **10**A and **10**B illustrate the cavity **190** in greater detail. As shown, the cavity **190** is fluidly open to the curved channel **180**, and thus to the access cannula **30**. With specific reference to FIG. **10**A, the cavity **190** is formed at the target site **172**, but is laterally offset from the central axis C of the access cannula **30**. This offset positioning is achieved via the curved shape of the channel **180**. A magnitude of the transverse offset is a function of the radius of curvature of the channel **180**, as well as an arc length thereof. The cavity **190** can have a variety of different shapes as dictated by a configuration of the working end **112** (FIG. **9**A). In some embodiments, the working end **112** can be configured to create the cavity **190** as having a discernable length L. With these optional embodiments, the cavity **190** is spatially oriented such that a direction of the length L is not parallel with the access cannula central axis C.

Curable material is subsequently delivered to the cavity **190**. For example, in some embodiments and with reference to FIG. **11**, the channel forming device **24** is re-introduced through the access cannula **30**, and positioned as shown. The source **130** of curable material (FIG. **1**) is fluidly connected to the channel forming device **24** and curable material **192** injected or dispensed into the cavity **190** via the side orifice(s) **70**. Alternatively, a component apart from the channel forming device **24** can be employed to inject or deliver the curable material **192**.

The systems and methods of the present disclosure provide a marked improvement over previous designs. By forming a curved channel within the cancellous bone and through which the cavity forming device is internally located facilitate formation of the cavity at a desired location that is otherwise offset from the central axis of the access cannula.

Although the present disclosure has been described with reference to preferred embodiments, workers skilled in the art

will recognize that changes can be made in form and detail without departing from the spirit and scope of the present disclosure.

What is claimed is:

1. A method of injecting curable material to a delivery site within a bone structure, the method comprising:

locating a distal end of an access cannula within the bone structure, the access cannula forming a lumen and defining a central axis; inserting a channel creating device into the lumen;

distally advancing a distal segment of the channel creating device from the distal end and into the bone structure;

creating a curved channel in the bone structure with the distally advancing distal segment, the curved channel defining a curve relative to the central axis; removing the channel creating device;

wherein the distal segment includes a shaft terminating at a distal tip, wherein a maximum outer diameter of the distal tip is greater than an outer diameter of the shaft, and further wherein the step of distally advancing the distal segment includes the distal tip boring through the bone structure;

inserting a distal portion of a cavity creating device into the lumen, the distal portion including an expandable body carried by an elongated body, the expandable body operable between a contracted state and an expanded state;

distally advancing the distal portion from the distal end, including the distal portion following a path of the curved channel; operating the expandable body to form a cavity in the bone structure, the cavity being open to the curved channel; and

delivering curable material to the cavity.

2. The method of claim **1**, wherein the expandable body is a balloon.

3. The method of claim **2**, wherein operating the expandable body to form a cavity includes inflating the balloon.

4. The method of claim **1**, wherein the step of the distal portion following a path of the curved channel includes the distal portion deflecting in response to contact with a wall of the curved channel.

5. The method of claim **4**, wherein the wall of the curved channel is defined by the bone structure.

6. The method of claim **4**, wherein the elongated body of the distal portion is a flexible catheter.

7. The method of claim **1**, wherein the distal segment of the channel creating device has a shape memory characteristic and naturally assumes a curved shape in longitudinal extension.

8. The method of claim **7**, wherein the step of inserting the distal segment into the lumen includes the access cannula forcing the distal segment to deflect from the curved shape toward a straightened shape.

9. The method of claim **7**, wherein the step of distally advancing the distal segment includes at least a portion of the distal segment distal the distal end of the access cannula naturally reverting toward the curved shape.

10. The method of claim **1**, wherein the maximum outer diameter of the distal tip is less than a diameter of the access cannula lumen.

11. The method of claim **1**, wherein the distal tip is sharpened.

12. The method of claim **1**, wherein the distal tip is asymmetric relative to a centerline of the shaft.

13. The method of claim **1**, wherein the shaft is tubular and forms at least one port adjacent the tip, the further wherein the step of delivering curable material includes reintroducing the channel creating device into the access cannula and delivering the curable material through the at least one port.

14. The method of claim **1**, wherein the curved channel has a diameter commensurate with a maximum diameter of the distal tip, and further wherein the cavity is defined by a maximum dimension greater than the curved channel diameter.

15. The method of claim **1**, wherein the bone structure is a vertebrae.

16. The method of claim **1**, wherein the bone structure includes an outer wall surrounding cancellous bone, and further wherein the curved channel is created in the cancellous bone independent of any naturally-occurring pathways in the cancellous bone.

* * * * *